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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/514,999	02/29/00	TANIMOTO	Y KODA20A.001A

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EXAMINER

MARX, I

ART UNIT	PAPER NUMBER
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1651

DATE MAILED:

06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/514,999

Applicant(s)
Tanimoto et al.

Examiner
Irene Marx

Art Unit
1651



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 20) ☐ Other: _____

The application should be reviewed for errors and conformity with domestic practice.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing in the omission of "said" or "the" before "polyamine" at line 2.

Claim 3 is confusing in the use of the term "autolization". Replacement with --autolysis-- would be remedial.

Claim 4 is confusing in that it is uncertain whether the nuclease treatment occurs at the recited pH range and temperature or whether the solution is submitted to this treatment before or after the nuclease reaction.

Claim 5 is confusing in the use

In claim 3, the phrase "and others" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

The claim is confusing because it is also unclear what is intended by "wherein the yeast somatic components are prepared from... by..", since yeast biomass is usually prepared by culturing in a culture medium. If "obtained" is intended, the claim should be amended accordingly. It should be clarified whether the preparation steps are intended before or after the digestion treatment. The process steps are not clearly delineated.

Claim 8 is confusing in that the nature of the intended autolysis accelerator is unclear.

Claims 1-8 are confusing in the use of the of a wavy line rather than a dash to indicate ranges. Replacement with dashes would be remedial.

The recitation of "torula" yeast in claim 3 renders the claim confusing, since the type of yeast, such as genus or species intended is unclear. Also the distinction between "wine" and "beer" yeast is unclear, since it is apparent that both are *Saccharomyces cerevisiae*.

Claim 7 is confusing in the language "a common salt". The intended "common" salt is not clear from the context.

Claims 6-8 fail to find proper antecedent basis in claim 3 for an extraction process. Claim 3 is directed to a method wherein "yeast somatic components are prepared".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(e) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakabayashi.

The reference teaches a method for the manufacture of a polyamine containing composition wherein yeast somatic components of a yeast such as *Candida utilis* are hydrolyzed using alkali and physical crushing, and wherein nitrogenous compounds are recovered, inherently containing polyamines (See, e.g., example 7). At Table 2, the conditions of treatment are outlined.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Sato *et al.*

The claims are directed to a process of producing polyamines wherein the polyamine is recovered after a hydrolysis step with alkali.

Sato *et al.* disclose a process of producing polyamines wherein the polyamine is recovered after treatment with a 10-30% sodium hydroxide solution for neutralization purposes. It is submitted that this step results in hydrolysis of yeast somatic components at least to some extent (See, e.g., Abstract).

Claims 1, 2, 3, 4, 5 and 8 rejected under 35 U.S.C. 102(b) as being anticipated by Tanekawa *et al.*

The reference teaches a method for the manufacture of a polyamine containing composition wherein yeast somatic components of a yeast are hydrolyzed using alkali and wherein the hydrolyzates are recovered, inherently containing polyamines (See, e.g., example 1). Note the use of an autolysis accelerator (col. 3, lines 14-17)

Claims 1, 3, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kanegae *et al.*

The reference teaches a method for the manufacture of a polyamine containing composition wherein yeast somatic components of a yeast are hydrolyzed using alkali and wherein the hydrolyzates are recovered, inherently containing polyamines (See, e.g., example 3).

Claims 1-5 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato *et al.* (Snow Brand Milk Products,) taken with Nakabayashi, Tanekawa *et al.*, Ajinomoto and Sugimoto.

Sato *et al.* disclose a process of producing polyamines wherein the polyamine is recovered after treatment with a 10-30% sodium hydroxide solution for neutralization purposes. It is submitted that this step results in hydrolysis of yeast somatic components at least to some extent (See, e.g., Abstract).

The reference appears to differ from the claimed invention in that the yeast the hydrolysis is not clearly effected with alkali or with digestion with a nuclease, but rather that the process of extraction is carried out under acidic conditions.

However, Nakabayashi teaches a method of hydrolysis for yeast components wherein yeast somatic components of *Candida utilis* are hydrolyzed using alkali and physical crushing, and wherein nitrogenous compounds are recovered, which naturally contains polyamines (See, e.g., example 7). At Table 2, the conditions of treatment are outlined.

In addition, Tanekawa *et al.* teaches a method for the manufacture of a yeast component hydrolyzate wherein yeast somatic components are hydrolyzed using alkali (See, e.g., example 1) and wherein an autolysis accelerator is added (col. 3, lines 14-17). Tanekawa *et al.* also disclose the use RNA-decomposing enzymes contained in yeast cells for the autolysis process (See, e.g., col. 3, lines 62-65 and Col. 4, lines 17-30). The reference also demonstrates that a stimulator or accelerator of autolysis such as ethyl acetate, is routinely used in the autolysis process (See, e.g., col. 3, lines 30-40). In addition, Tanekawa teaches the use of heating as a means of obtaining autolyzed products of yeast cells. See, e.g., col. 3, lines 15-17 and 40-45, and example 1. For the use of sodium chloride in the process, see, e.g., col. 3, lines 45-48.

In addition, Ajinomoto teach the use of an accelerator for autolysis to produce a solution of yeast components, which, of course, contain polyamines and Sugimoto *et al.* teach the addition of sodium chloride to yeast to effect lysis and wherein the process occurs at about 100°C and at pH 4. The concentration of sodium chloride and other process parameters appear to be at the required level. However, even if it is not the adjust of conditions identified as result-effective variables cited in the reference would have been prima facie obvious to a person having ordinary skill in the art for optimization purposes.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of obtaining polyamines from yeast somatic components as disclosed by Sato *et al.* by carrying out the hydrolysis under alkaline conditions and using various additions of salts and/or enzymes as disclosed by Nakabayashi, Tanekawa *et al.*, Ajinomoto and Sugimoto in view of the expected benefit of obtaining a greater yield of solid matter containing polyamines in the solution as suggested by Tanekawa *et al.* (See, e.g., col. 4, lines 10-12).

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable Sato *et al.* (Snow Brand Milk Products,) taken with Nakabayashi, Tanekawa *et al.*, Ajinomoto and Sugimoto as applied to claims 1-5 and 7-8 above, and further in view of Iijima (JP 09117263) and Stanzl *et al.*.

The references differ from the claimed invention in the extraction of yeast somatic components by using crushing in a high pressure homogenizer or sonication. However Iijima teach a process of extraction of yeast somatic components by using crushing in a high pressure homogenizer (See, e.g., Abstract). and Stanzl *et al.* adequately demonstrate the use of ultrasonic disintegration to obtain somatic components from yeasts (See, e.g., Example 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Iijima or Stanzl *et al.* according to the teachings of Sato *et al.*, Nakabayashi, Tanekawa *et al.*, Ajinomoto and Sugimoto discussed above by using crushing in a high pressure homogenizer or sonication as methods of obtaining yeast somatic components from yeast cells.

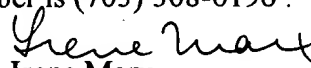
Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196 .


Irene Marx
Primary Examiner
Art Unit 1651